



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/341,590	07/13/99	LARSEN	PPT-20479-US

VB

CHERYL H AGRIS
PO BOX 806
PELHAM NY 10803

HM12/1108

EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

14

DATE MAILED: 11/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
---------------	-------------	-----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

9

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Applicants' species election (paper No. 13, filed 8/24/00) is acknowledged

[Leu-enkephalin-(Lys)₆]

However, additional peptide sequences are required, as indicated on the attached sheets.

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See comments below.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

Further sequence listings are required. The claims encompass conjugates in which "X" can be any of the following:

enkephalin, Leu-enkephalin, Met-enkephalin, endothelin, vasoactive intestinal peptide, substance P, neurotensin, endorphin, insulin, gramicidin, paracelsin, delta-sleep inducing peptide, angiotensin-I, angiotensin-II, angiotensinogen, angiotensinogen, vasopressin, oxytocin, calcitonin, calcitonin gene-related peptide, calcitonin gene-related peptide-II, parathyroid hormone (1-34), parathyroid hormone

related peptide, EMP-1, atrial natriuretic peptide, brain natriuretic peptide, C-type natriuretic peptide (1-53), "mini-ANP", cecropin, kinetensin, neurophysins, elafin, guamerin, atriopeptin-I, atriopeptin-II, atriopeptin-III, deltorphin-I, deltorphin-II, vasotocin, bradykinin, dynorphin, dynorphin-A dynorphin-B, GRH, GH releasing factor, GH releasing peptide, growth hormone, tachykinin, ACTH, cholecystokinin, corticotropin releasing factor, diazepam binding inhibitor fragment, FMRF-amide, leupeptin, sandostatin, galanin, gastric releasing peptide, gastric inhibiting polypeptide, glucagon, glucagon-like peptide -1, glucagon-like peptide-2, exendin-3, exendin-4, LHRH, melanin concentrating hormone, melanocyte stimulating hormone, alpha-MSH, morphine modulating peptide, somatostatin, substance K, TRH, Kyotorphin, melanostatin, hirulog, hirulog-1, melanotan-II, thymosin alpha-1, ornipressin, octreotide, motilin, neurokinin-A, neurokinin-B, neuromedin B, neuromedin C, neuromedin K, neuromedin N, neuromedin U, neuropeptide K, neuropeptide Y, PACAP, pancreatic polypeptide, peptide YY, peptide histidine methionine amide, secretin, thrombopoietin, insulin-like growth factor-I, insulin-like growth factor II, GHRP-6, interleukin-II, beta-interleukin-I, beta-interleukin-II, epidermal growth factor (20-31), eptifibatide, endomorphin-1, endomorphin-2, adrenomodulin, antiarrhythmic peptide, antagonist G, indolicin, osteocalcin, cortistatin-29, cortistatin-14, PD-145065, PD-142893, fibrinogen binding inhibitor peptide, leptin 93-105, GR 83074, and Tyr-W-MIF-1.

A sequence listing has been provided for many of these; however, applicants have failed to provide a sequence listing for all of them. A sequence listing is required for each of the foregoing peptides (that has not already been provided). The sequence listing will aid in the search. Applicants may argue that it is possible for the examiner to find each of the sequences. It is true that, given sufficient time and effort, a reference teaching the sequence could be found for each. However, given that a search of the claimed invention already exceeds the "undue burden" threshold, the additional time required to find all of the sequences would be entirely unreasonable.

Serial No. 341,590

-4-

Art Unit 1653

[If any of the foregoing peptides are not of interest at the present time, applicants can delete them from the claims, i.e., specifically exclude them from the independent claims, and eliminate their recitation from all dependent claims. If this is done, there will be no need for the sequence listings of those peptides that have been excluded].



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: See accompanying sheets

Applicant Must Provide